Complete Summary

GUIDELINE TITLE

Water and enteral formula safety and stability. In: A.S.P.E.N. enteral nutrition practice recommendations.

BIBLIOGRAPHIC SOURCE(S)

Bankhead R, Boullata J, Brantley S, Corkins M, Guenter P, Krenitsky J, Lyman B, Metheny NA, Mueller C, Robbins S, Wessel J. Water and enteral formula safety and stability. In: A.S.P.E.N. enteral nutrition practice recommendations. JPEN J Parenter Enteral Nutr 2009 Mar-Apr;33(2):132-42. [76 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Conditions or disease states requiring enteral nutrition

GUIDELINE CATEGORY

Management
Prevention

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Geriatrics
Infectious Diseases
Internal Medicine
Nursing
Nutrition
Pediatrics
Pharmacology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Pharmacists
Physician Assistants
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

- To examine the available literature related to the preparation andÂ delivery of enteral nutrition
- To establish evidence-based practice guidelines for the safe and effective use of enteral nutrition

TARGET POPULATION

Patients in need of enteral nutrition throughout the lifecycle and throughout all practice settings

INTERVENTIONS AND PRACTICES CONSIDERED

Enteral nutrition (EN) formula preparation, reconstitution, distribution, storage, handling, decanting, administration, and hang time, including:

1. Water safety in reconstitution and dilution
2. Prevention of microbial contamination
3. Human breast milk preparation, storage, and administration
4. Hang time for EN formulas and administration sets
5. EN formula inventory turnover
6. Sterile, liquid EN formulas versus powdered, reconstituted formulas
7. Use of di(2-ethylhexyl) phthalate (DEHP)-free products for pediatric patients

MAJOR OUTCOMES CONSIDERED

- Frequency of contamination of enteral nutrition (EN) formula
- Patient infections attributed to use of EN
- Time EN formula and human breast milk (HBM) remain pathogen free
- Time administration sets remain pathogen free
- Self-life of nutrients in EN formula

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

PubMed was used to search and collect the literature. Search was limited to English language journals and abstracts were excluded. All types of literature including research, case reports, and review articles. Government, regulatory, and standard setting websites such as the Unites States (US) Food and Drug Administration (FDA), US Pharmacopeia, and The Joint Commission for Accreditation of Healthcare Organizations were also utilized. Search terms included enteral nutrition, tube feeding, enteral complications, enteral safety, water safety, medication administration, enteral access device, aspiration, misconnections, enteral microbial growth, infant formulas, medical foods, and enteral formulary.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The literature and evidence were classified based on the Agency for Healthcare Research and Quality (AHRQ) method.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) established the Enteral Nutrition Practice Recommendations Task Force to examine the available literature related to the ordering, preparation, delivery, and monitoring of enteral nutrition and to establish evidence- based practice guidelines. It was recognized from the onset that there was either an absence of research or the research was of limited strength to support many aspects surrounding the practice of administering enteral nutrition. Therefore, in addition to the existing literature, a consensus of expert opinion based on current knowledge and best practices was used to formulate these practice recommendations.

The strength of each practice recommendation was graded using a method consistent with the 2002 A.S.P.E.N. Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients. The grading system was based on a modified version of the method used by the Agency for Healthcare Research and Quality (AHRQ), United States (US) Department of Health and Human Services. After review of the literature cited, the authors used the AHRQ criteria to classify the strength of the evidence supporting each recommendation statement.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation

A. There is good research-based evidence to support the guideline (prospective, randomized trials).
B. There is fair research-based evidence to support the guideline (well-designed studies without randomization).
C. The guideline is based on expert opinion and editorial consensus.

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft document was sent to leaders of American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Clinical Practice Sections, Clinical Practice Committee, and Board of Directors for review and comment process.

The draft document was also sent to leaders of related medical organizations. Reviews were received back from the following groups: American Society of

Health-System Pharmacists (ASHP), Institute of Safe Medication Practices (ISMP), North American Society for Pediatric Hepatology, Gastroenterology, and Nutrition (NASPHGAN), American Academy of Pediatrics (AAP), Dietitians in Nutrition Support, a dietetic practice group of the American Dietetics Association, and U.S. Pharmacopeia (USP).

The document was approved by the A.S.P.E.N. Board of Directors following review by internal and external content experts and the A.S.P.E.N. Clinical Practice Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of recommendations (**A-C**) are provided at the end of the "Major Recommendations" field.

Practice Recommendations

1. Each institution should define an ongoing quality control process for enteral nutrition (EN) formula preparation, distribution, storage, handling, and administration. **(B)**
2. Institutions should maintain written policies and procedures for safe EN formula and human breast milk (HBM) preparation and handling, as well as maintain an ongoing surveillance program for contamination. These should be based on the American Dietetic Association (ADA) infant feeding guidelines, Hazard Analysis Critical Care Points (HACCP), and the United States Pharmacopeia (USP) good compounding practices. **(B)**
3. EN formulas should be prepared for patient use in a clean environment using aseptic technique by specially trained personnel. Strict aseptic technique should be used in the preparation and administration of enteral formulas. **(A)**
4. All personnel involved in preparing, storing, and administering EN formulas and HBM should be capable and qualified for the tasks, and follow accepted best practices. **(C)**
5. Sterile, liquid EN formulas should be used in preference to powdered, reconstituted formulas whenever possible. **(A)**
6. Store unopened commercially-available liquid EN formulas under controlled (dark, dry, cool) conditions. **(B)**
7. Maintain a rapid enteral feeding formula inventory turnover well within the product´s expiration date. **(C)**
8. Formulas reconstituted in advance should be immediately refrigerated, and discarded within 24 hours of preparation if not used; formulas should be exposed to room temperature for no longer than 4 hours, after which they should be discarded. **(B)**
9. Use a purified water or sterile water for irrigation supply for formula reconstitution and medication dilution. Consider purified water for enteral access device flushes in at-risk patients. **(B)**
10. Strict adherence to manufacturer´s recommendations for product use results in less contamination of EN. **(B)**
11. Use of disposable gloves is recommended in the administration of EN. **(A)**
12. Formula decanted from a screw cap is preferable instead of a flip top. **(A)**

13. A recessed spike on a closed system container is preferable. **(B)**
14. A feeding pump with a drip chamber prevents retrograde contamination of the EN formula from the feeding tube. **(A)**
15. Sterile, decanted formula should have an 8-hour hang time unless used for a neonate where hang time should be limited to 4 hours. **(B)**
16. Administration sets for open system enteral feedings should be changed at least every 24 hours. **(B)**
17. Powdered, reconstituted formula, HBM, and EN formula with additives should have a 4-hour hang time. **(C)**
18. Closed-system EN formulas can hang for 24-48 hours per manufacturer's guidelines. **(A)**
19. Administration sets for closed-system EN formula should be changed per manufacturer guidelines. **(A)**
20. Administration sets for HBM should be changed every 4 hours. **(C)**
21. All products used for pediatric patients should be di(2-ethylhexyl) phthalate (DEHP) free. **(B)**

Summary

The complexity of EN feedings cannot be underestimated. All healthcare professionals should be vigilant in continuous surveillance of high risk practices, products and systems as they relate to the enterally fed patient. Recognition of ordering, administration, and monitoring steps of EN delivery which may increase risk of complications to the enterally fed patient is essential.

Definitions:

Grade of Recommendation

A. There is good research-based evidence to support the guideline (prospective, randomized trials).
B. There is fair research-based evidence to support the guideline (well-designed studies without randomization).
C. The guideline is based on expert opinion and editorial consensus.

CLINICAL ALGORITHM(S)

The original guideline document contains clinical algorithms for:

- Potential Points for Contamination in the Preparation, Storage, Handling, and Administration of Enteral Nutrition
- Formula Hang Time Based on Source of Preparation

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence ranges from prospective randomized trials to expert opinion/consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Standardized processes for enteral nutrition care including ordering, preparation, administration, and monitoring
- Optimal care and minimal risk of error

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

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Enteral nutrition is contraindicated in a patient with significant hemodynamic compromise.

QUALIFYING STATEMENTS

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The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Enteral Nutrition Practice Recommendations are based upon general conclusions of health professionals who, in developing such recommendations, have balanced potential benefits to be derived from a particular mode of providing enteral nutrition with known associated risks of this therapy. The underlying judgment regarding the propriety of any specific practice recommendation or procedure shall be made by the attending health professional in light of all the circumstances presented by the individual patient and the needs and resources particular to the locality. These recommendations are not a substitute for the exercise of such judgment by the health professional, but rather are a tool to be used by the health professional in the exercise of such judgment. Use of this document is voluntary and should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed toward obtaining the same result.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Slide Presentation

Staff Training/Competency Material
Wall Poster

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Bankhead R, Boullata J, Brantley S, Corkins M, Guenter P, Krenitsky J, Lyman B, Metheny NA, Mueller C, Robbins S, Wessel J. Water and enteral formula safety and stability. In: A.S.P.E.N. enteral nutrition practice recommendations. JPEN J Parenter Enteral Nutr 2009 Mar-Apr;33(2):132-42. [76 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Jan

GUIDELINE DEVELOPER(S)

American Society for Parenteral and Enteral Nutrition - Professional Association

SOURCE(S) OF FUNDING

American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.)

GUIDELINE COMMITTEE

The Enteral Nutrition Practice Recommendations Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Robin Bankhead, CRNP, MS, CNSN, *Chair*; Joseph Boullata, PharmD, BCNSP; Susan Brantley, MS, RD, LDN, CNSD; Mark Corkins, MD, CNSP; Peggi Guenter, PhD, RN, CNSN; Joseph Krenitsky, MS, RD; Beth Lyman, RN, MSN; Norma A. Metheny, PhD, RN, FAAN; Charles Mueller, PhD, RD, CNSD; Sandra Robbins, RD, CSP, LD; Jacqueline Wessel, MEd, RD, CSP, CNSD, CLE

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Jacqueline Wessell is on the Abbot Nutrition Speakers Bureau. No other potential conflicts were reported.

ENDORSER(S)

American Dietetic Association - Professional Association
American Society of Health-System Pharmacists - Professional Association
Institute for Safe Medication Practices - Professional Association

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society for Parenteral & Enteral Nutrition (A.S.P.E.N.) Web site.

Print copies: Available in hardcopy from A.S.P.E.N. Telephone: 1-800-727-4567.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Be A.L.E.R.T. and Be A.W.A.R.E. Enteral Safety Campaign Posters. Available from the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Web site
- A CD-ROM tutorial: writing parenteral nutrition (PN) orders. Available from the A.S.P.E.N. Web site.
- Slide teleseminars are available to members for purchase from the A.S.P.E.N. Web site.

In addition, the following forms are available in the original guideline document:

- Adult Enteral Nutrition Order Form
- Pediatric Enteral Nutrition Order Form
- Standard Enteral Nutrition Label Template (Adult Patient)
- Standard Human Breast Milk Label Template (Infant Patient)
- Human Breast Milk Storage Label

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 5, 2010. The information was verified by the guideline developer on March 15, 2010.

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